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UNCLAS CARACAS 001332

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USDOC FOR 6132/MAS/MFG/OHCG/SFRANCIS USDOC FOR 3134/OIO/WH/DDEVITO

E.O. 12958: N/A TAGS: <u>BEXP</u> <u>ETRD</u> <u>VE</u>

SUBJECT: IMPORT REGULATIONS FOR USED MEDICAL EQUIPMENT

REF: USDOC 00292

11. The questions asked in reftel will be answered in the same sequence:

A.There are no special regulations or customs tariffs that apply to used or refurbished medical equipment, which do not apply to used of refurbished medical equipment, which do not apply to new products. No customs duties discounts are granted for the import of used equipment. However, internal regulations within the government prohibit all government entities or operations from importing or using used equipment. While not subject to laws or regulations, private banks upon financing the acquisition of medical equipment as a rule will not grant financing to imports of used or refurbished equipment. We have heard of some isolated cases, where a bank will entertain a request for financing if the refurbished equipment is covered by warranties. B.If a medical device has been registered and authorized for sale by the Ministry of Health and has been given its registration number, refurbished equipment of the same type can be legally imported by another company. However, if the refurbishment included improvements or changes affecting key components or if the application of the equipment is different from the originally registered one, the importer should request a reading from the Ministry to determine whether a new application for registration would be required. C.Public health institutions owned by a government agency including military are not allowed to buy and use refurbished or used medical devices. D.There is a somewhat limited market for used or refurbished medical equipment among the smaller private hospitals and clinics or among individual physicians. Most of these potential buyers, however, will require the availability in the country of spare parts, service and in some cases a limited warranty. The used equipment market is driven mainly by the cost difference between used and new equipment. E.The potential market for used medical equipment consists mainly of electro-medical or other more expensive pieces of equipment, such as x-ray machines including dental units, electrocardiographs, ultrasound equipment, sterilizers, laparoscopy and colon or stomach viewers but normally does not include medical/surgical instruments. F. There appears to be no reprocessing on an industrial scope of single-use devices nor does there appear to be a commercial scale of sales of such reprocessed single use

devices. Individual doctors and some of the very small clinics might at times wash and re-sterilize such devices if they are

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considered to be in good enough condition.